Rotablator™
Rotational Angioplasty System

Console

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Boston Scientific

Rotablator™ Rotational Angioplasty System

Description

The Rotablator Rotational Angioplasty System is a catheter-based angioplasty device utilizing a diamond-coated elliptical burr at the tip of a flexible drive shaft. Tracking coaxially over a guide wire and rotating at up to 190,000 RPM, the burr ablates plaque into fine particles that are disposed of by the body's reticuloendothelial system. The three main components included in the system are the guide wire, control console system, and the advancer/catheter.

The Rotablator Console monitors and controls the rotational speed of the burr and provides the operator with performance information throughout the procedure. In the control console, the gas is filtered and then regulated by a fixed-pressure regulator. The resultant pressure is gated by a pilot-actuated valve, and gas flow is automatically adjusted by a proportional pneumatic valve in order to maintain proper Rotablator System operating speed. The gas then enters the gas turbine, and after expanding in the turbine, is exhausted at the bottom of the Rotablator Rotational Angioplasty System advancer. Compressed gas is also supplied to the foot pedal through a triple hose. When the foot pedal is depressed, the gas is returned to the console, where it activates the pilot valve, permitting flow of regulated compressed gas to the Rotablator Rotational Angioplasty System advancer via the front panel turbine connector. With this pilot valve arrangement, the gas flow to the Rotablator Rotational Angioplasty System advancer cannot be throttled by using the foot pedal.

Intended Use

The Rotablator Console is intended for use with the Rotablator Rotational Angioplasty System. Refer to guide wire and advancer package inserts for specific information on the use of these components.

Restrictions, Warnings and Precautions

Restrictions

℞ ONLY Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. For coronary use, federal (USA) law further restricts this device to a physician trained and/or experienced in coronary balloon angioplasty. Governing law outside the USA restricts this device to sale by or on the order of a physician.

Warnings

- Never use oxygen as the propellant for the Rotablator Rotational Angioplasty System. Never connect the regulator to an oxygen cylinder. Oxygen combined with oil or other combustibles in the system can result in an explosion.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Rotablator System as replacement parts for internal components, may result in increased emissions or decreased immunity of the Rotablator System.
- The Rotablator System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Rotablator System should be observed to verify normal operation in the configuration in which it will be used.
- This device is not to be used in the presence of flammable anesthetics.
- If a hissing noise is detected from the console, check to make sure that the pressure of the gas supplied to the air or nitrogen connector does not exceed 758.4 kPa (110 psi). The console is equipped with a pressure relief valve to protect against excessive inlet pressure. Do NOT operate the Rotablator Console with gas pressures in excess of 758.4 kPa (110 psi), as a gas hose may burst.
- If patient defibrillation becomes necessary, the physician should take the appropriate measures to protect himself against electrocution from the defibrillator.
- Do not modify or repair. Modification or repair of the instrument by a person other than an authorized Boston Scientific representative may compromise the integrity of the device and/or lead to device failure which, in turn, may result in patient injury or death. Boston Scientific assumes no liability with respect to any instrument which has been modified or repaired by a person other than an authorized Boston Scientific representative and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments. If repair is needed, call your Boston Scientific representative.

Precautions

- Care must be taken not to spill saline or other fluids on the console. Saline spilled in the console may result in corrosion or electrical hazard.
- User should take precautions when using the console in conjunction with other medical electrical equipment, as electromagnetic interference between the equipment may affect the performance of the console or other devices. The console complies with IEC 60601-1-2 regulations for radiation of and immunity from electromagnetic energy.
- The Rotablator Console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix D.
- Portable and mobile RF communications equipment can affect the Rotablator Console.

Description of the Rotablator Console

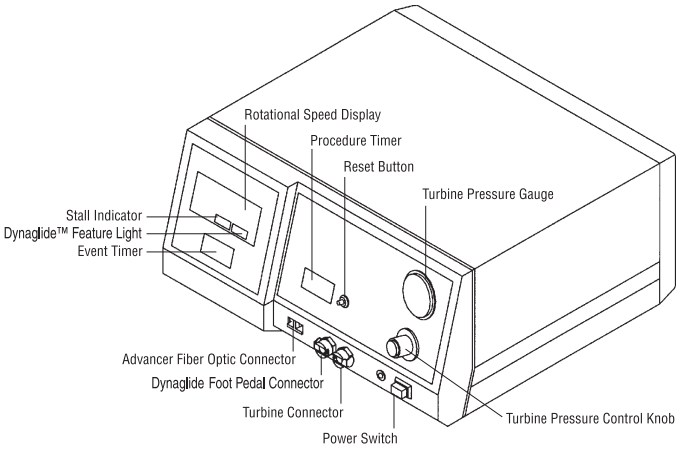

Figure 1
Control Console Front Panel

The symbols used on the console are listed in Appendix A. The main features and functions of the console shown in Figure 1 are described below.

Front Panel

- **Power Switch:** Power is supplied to the console when the switch is in the depressed position. The push button power switch is located in the lower right corner of the front panel. The green light to the left of the switch illuminates to indicate that the power has been turned on.
- **Turbine Pressure Control Knob:** The knob located above the power switch is used to adjust the gas pressure to the turbine and consequently, the rotational speed. Turning the knob clockwise increases the turbine pressure (speed) as indicated on the turbine pressure gauge. Counterclockwise rotation decreases the turbine pressure (speed).
- **Turbine Pressure Gauge:** Located above the turbine pressure control knob, the pressure gauge displays the pressure of the compressed gas being supplied to the advancer gas turbine. Generally the greater the gas pressure to the gas turbine, the higher the rotational speed. The pressure should not be allowed to exceed 482.6 kPa (70 psi) during normal operation. Flow restrictions have been incorporated into the pneumatic system to prevent the delivery of excessive energy to the advancer. For additional information on operating range, accuracy and precision, see Table 1.
- **Rotational Speed Display (Tachometer):** The rotational speed display located in the upper left corner of the console indicates the speed in RPM of the burr and gas turbine. When the gas turbine is not operating, the display is blank. When the foot pedal is depressed, the rotational speed is shown on the rotational speed display. For additional information on operating range, accuracy and precision, see Table 1.
- **STALL Light:** The STALL light is located directly below the rotational speed display, and is visible only when illuminated. If the rotational speed of an advancer falls below 15,000 RPM for more than 0.5 second, the red STALL light is illuminated and delivery of compressed gas to the advancer is discontinued. A stall condition may also be detected if the fiber optic connection is not properly engaged. Stall detection is a safety feature designed to discontinue delivery of compressed gas to the advancer in the event of excessive mechanical loading or incorrect connection of the fiber optic. Releasing the foot pedal will clear the stall condition and extinguish the STALL light.

- **DYNAGLIDE™ Feature Light:** The DYNAGLIDE Feature light is located adjacent to the STALL light, and is visible only when illuminated indicating that the Dynaglide Feature is activated. The Dynaglide Feature provides a controlled low speed rotation (approximately 50,000-90,000 RPM) of the Rotablator™ Burr for use during intraprocedure exchange of Rotablator Rotational Angioplasty System advancer or catheter. The Dynaglide Foot Pedal button is used to turn the Dynaglide Feature on or off.
- **Event Timer:** Located below the tachometer, the event timer records how long the foot pedal has been continuously depressed with the air turbine and burr spinning. When the foot pedal is released, the timer continues to display the previous event time. Depressing the foot pedal resets and restarts the timer. For additional information on operating range, accuracy and precision, see Table 1.
- **Procedure Timer:** The procedure time is the sum of the individual event times and indicates the total time the burr has been spinning during the procedure. For additional information on operating range, accuracy and precision, see Table 1.

Table 1

Display	Operating Range	Accuracy	Precision
Turbine Pressure Gauge	0-689.5 kPa or 0-100 psi	± 5%	6.9 kPa or 1 psi
Rotational Speed Display	0-250,000 RPM	± 1.5%	1,000 RPM
Event Timer	00:00-59:59	± 0.1%	1 second
Procedure Timer	00:00-59:59	± 0.1%	1 second

- **Reset Button:** Pushing the reset button resets the event and procedure timers to zero.
- **Turbine Connector:** The gas line connector on the right-hand side receives the advancer gas hose and supplies filtered, regulated compressed gas to the advancer when the foot pedal is depressed.
- **Dynaglide Foot Pedal Connector:** The gas line connector on the left-hand side receives the Dynaglide Foot Pedal pink hose, and is used to activate or deactivate the Dynaglide Feature mode of operation.
- **Fiber Optic Tachometer Cable Connector:** These two female connectors receive the mating male connectors from the fiber optic tachometer cable. The orientation of the cable to the female connector is not important. The fiber optic tachometer cable carries light pulses which the console uses to determine the rotational speed of the gas turbine and burr.

Rear Panel

- **Line Cord:** This cable plugs into a conventional 100-120 V a.c. or 220-240 V a.c. receptacle (as indicated on the name plate located on the rear of the console) and provides power to the console. In Germany, line cord connections must be to a VDE 0107 compliant installation. The ground wire of the line cord is internally connected to the console chassis.
- **Fuses:** The fuses protect the console's electrical components in the event of a serious electrical fault. If a fuse should fail, refer to Appendix B for replacement instructions.
- **Potential Equalization Connector:** Located to the left of the fuse, the potential equalization connector is provided to allow potential equalization between various hospital electrical instruments. In Germany, the potential equalization connections must be made to a VDE 0107 compliant installation.
- **Compressed Gas Inlet:** This male connector, located in the top center of the rear panel, mates to the corresponding connector on the supply line from the compressed gas source. Pressure at this inlet should always be between 620.5 and 758.4 kPa (90 and 110 psi) with a minimum flow capacity of 140 l/min (5 standard cubic feet per minute (scfm)). Pressure will be reduced by the console to operating limits. An internal pressure-relief valve protects against input pressures in excess of 792.9 kPa (115 psi) and creates a loud hissing noise in the console when the pressure exceeds 792.9 kPa (115 psi).
- **Dynaglide Foot Pedal Connectors:** These two connectors receive the mating pair of connectors from the Dynaglide Foot Pedal. The green hose connects to the right-hand connector and the blue hose to the left-hand connector.

Other

- **Dynaglide Foot Pedal:** The foot pedal is used as an on/off control for the advancer gas turbine. The foot pedal is also fitted with a valve which vents any compressed gas in the foot pedal hose when the pedal is released, permitting the burr to stop rapidly. The foot pedal is mounted in a protective shroud which inhibits accidental actuation.
- The Dynaglide Foot Pedal button located on the right side of the foot pedal housing is used as an on/off control for the Dynaglide Feature mode of operation. When the Dynaglide Feature is on, the green DYNAGLIDE Feature light is illuminated on the console front panel.

Assembly and Setup of the Rotablator Console

The recommended control console system, illustrated in Figure 2, consists of an air or nitrogen pressure regulator mounted on a compressed gas cylinder, connected to the Rotablator Console via a supply hose (provided with the console). The gas cylinder is shown for illustration only, and is not of the recommended size. Gas cylinders must be properly secured per standard procedures.

Note: It may also be possible to operate this system from a hospital (house) gas system, as discussed in Appendix C. The Rotablator Console is not suitable for use with in-hospital (house) compressed gas lines in Germany due to pressure and flow incompatibilities, unless connections are made in accordance with DIN 13 260.

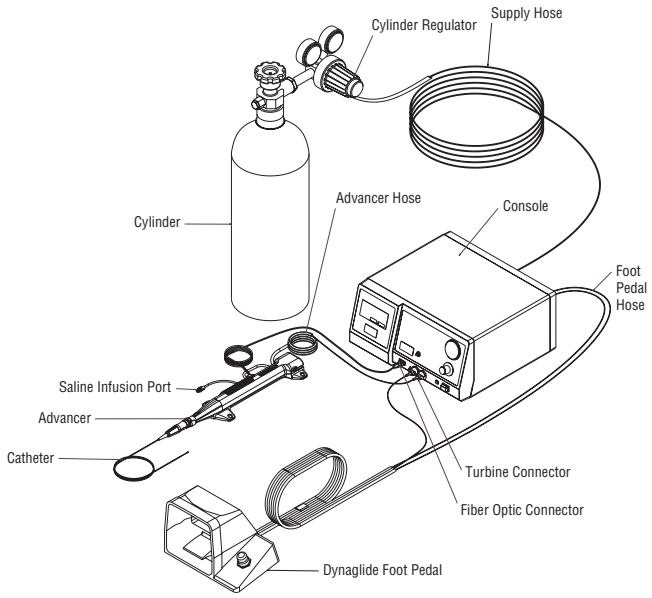

Figure 2
Control Console System

To put the Rotablator Console into service, proceed as follows:

WARNING NEVER use oxygen as the propellant for the Rotablator Rotational Angioplasty System. NEVER connect the regulator to an oxygen cylinder. Oxygen combined with oil or other combustibles in the system can result in an explosion.

WARNING This device is not to be used in the presence of flammable anesthetics.

1. **Procure a compressed gas cylinder containing either compressed air or nitrogen.**

   In Germany, only compressed air may be used, gas cylinder fittings must be according to DIN 477 Teil 1 (Druckluft), and compressed gas cylinders must be approved by the German government (Bauartzugelassen). A cylinder capacity of at least 2250 l (79.46 standard cubic feet) is recommended, and will provide approximately 20 minutes of service with the Rotablator Rotational Angioplasty System advancer running at full speed. Larger cylinders may be used. A fully charged spare cylinder should always be available.

2. **Secure the compressed gas cylinder in accordance with hospital procedures.**

3. **Obtain a cylinder regulator (relieving type is preferred) capable of delivering at least 140 l/min (5 scfm) at 620.5-758.4 kPa (90-110 psi).**

   Make certain that the cylinder regulator fitting is compatible with the gas cylinder being used. In Germany, only compressed air may be used, gas cylinder fittings must be according to DIN 477 Teil 1 (Druckluft), and compressed gas cylinders must be approved by the German government (Bauartzugelassen).

4. **Connect the supply hose gas coupling (provided with the Rotablator Console) to the outlet port of the cylinder regulator.**

   Unless local government regulations require otherwise, the gas coupling is configured with .6 cm (¼") MNPT threads. Verify the type of gas coupling provided with the Rotablator Console prior to procuring a cylinder regulator.

   If necessary, use suitable adapters to make the connection. In some countries, the regulator end of the gas supply hose has a permanently attached warning tag to remind users not to connect it to oxygen sources. Do NOT remove this tag.

5. **Remove the cylinder cap and attach the regulator, tightening the cylinder fitting firmly.**

   The regulator should be adjusted so that the outlet pressure is in the range 620.5-758.4 kPa (90-110 psi).

6. **Connect the supply hose to the inlet connector on the back of the console.**

   In most countries, the inlet connector is marked AIR OR NITROGEN. In Germany, the inlet connector is marked 'Druckluft'. Verify that the compressed gas being placed into service is in accordance with the inlet connector marking.

7. **Connect the foot pedal to the console by first locating the three connectors at the end of the foot pedal triple hose.**

   Insert the green hose connector in the right-hand and the blue hose connector in the left-hand mating receptacles on the rear of the Rotablator™ Console. These receptacles are labeled FOOT PEDAL or marked with a foot pedal symbol. Connect the pink hose connector to the left-hand connector on the front panel.

8. **Connect the power cord to a properly rated hospital grade receptacle (as indicated on the nameplate located on the rear of the console).**

   In Germany, power connections must be made to a VDE 0107 compliant installation, and the potential equalization stud must be connected.

9. **Open the compressed gas cylinder valve, or line valve if running on house air (see Appendix C), to supply compressed gas to the console.**

   Note that the cylinder regulator gauge indicates the pressure of the gas remaining in the cylinder. The regulator should be adjusted so that it never supplies more than 758.4 kPa (110 psi) to the console, and no less than 620.5 kPa (90 psi). Do not initiate the procedure if less than 3,447 kPa (500 psi) of gas remains in the tank.

WARNING **If a hissing noise is detected from the console, check to make sure that the gas pressure supplied to the air or nitrogen connector does not exceed 758.4 kPa (110 psi). The console is equipped with a pressure relief valve to protect against excessive inlet pressure. Do NOT operate the Rotablator Console with gas pressures in excess of 758.4 kPa (110 psi), as a compressed gas hose may burst.**

10. **Push the console power switch and confirm that the green light illuminates indicating power is on.**

    The Rotablator Console is now ready for use. Console placement, ventilation, splash protection and cleaning instructions may be found below in the section entitled: "Operation, Cleaning and Disposal Instructions."

Operation, Cleaning and Disposal Instructions

1. **Ventilation**

   The Rotablator Console uses natural convection cooling to maintain the proper operating temperature for internal components. Cooling vents are located on the bottom and rear of the console enclosure. In order to ensure proper ventilation of the console, it must be placed on a hard, flat surface with a minimum of 2.5 cm (1") clearance maintained around all sides and bottom of the enclosure. Do not set on drapes or bedding.

2. **Splash**

   The Rotablator Console is designed to be placed outside of the sterile field. Care should be taken to protect the console from splash and ingress of liquids which may cause damage to internal components.

3. **Cleaning**

   The Rotablator Console and Dynaglide™ Foot Pedal should be cleaned regularly by wiping with a soft cloth dampened with a mixture of water and mild detergent. Never immerse in fluids. The use of solvents or abrasive cleaners may cause damage to the plastic parts of the console and should be avoided.

4. **Disposal**

   The user should follow local and national regulations for disposal of electronics when disposing of this unit. The console contains no batteries or heavy metals.

References

For coronary use, please refer to the Rotablator Rotational Angioplasty System physician training program course materials for a listing of publications, or contact your local sales representative. Additional articles, including publications on the use of the Rotablator Rotational Angioplasty System in the peripheral vasculature are available upon request. Please contact your local sales representative to obtain a listing.

Appendix A - Symbol Translation Key

The symbols shown below may be present when required by specific safety testing agencies such as Underwriters Laboratories (UL), Canadian Standards Association (CSA), etc.


Dangerous voltage. To reduce risk of electric shock, do NOT remove cover. Refer servicing to qualified service personnel.


Potential equalization connector. Provides means of achieving potential equalization between hospital instruments. In Germany, connection must be to a VDE 0107 compliant installation.


Indicates that a fire hazard may exist if fuses are not replaced as marked.


Indicates type CF equipment.


Attention! Consult Accompanying Documents.


Console power is OFF when the power switch is in the OUT position.

Console power is ON when the power switch is in the IN position.

Rotational Speed. Displays speed of the burr in RPM.


Event Time. Displays the length of time the foot pedal has been continuously depressed.


Procedure Time. Displays the sum of the individual event times.


Reset. Resets the event and procedure timers to zero.


Turbine Pressure. Displays the pressure of the compressed gas being supplied to the advancer gas turbine.


Turbine pressure increases with clockwise rotation.


Fiber optic connector.


Turbine. Connector for the advancer gas hose.


Compressed Gas Inlet. Connector for the supply line from the compressed gas source.


Foot pedal connectors.


Proper disposal of electronic equipment is required according to EN directive 2002/96/EC, Waste of Electrical and Electronic Equipment (WEEE).


Contents of Package.

UPN Product Number.

The product has been tested for compliance with the applicable requirements of UL 60601-1:2003. Safety approval for the US has been granted by Underwriters Laboratories.

The product has been tested for compliance with the applicable requirements of CAN/CSA C22.2 No. 601.1. Safety approval for Canada has been granted by CSA.

EN 60601-1

Electrical safety testing was performed by TUV Rheinland.

Danger - Explosion Hazard.

Do not use in the presence of flammable anesthetics.

Store within the given relative humidity upper and lower limitations.

Appendix B - Service and Maintenance Information

Technical Specifications

Electrical Specifications:	Selectable Voltage:	100-120 V a.c. or 220-240 V a.c.
	Frequency:	50-60 Hz
	Power:	70 VA
	Fuses:	2 x F2.0A, 250V
Pneumatic Specifications:	Input Gas:	Compressed Air or Nitrogen
	Pressure:	620.5-758.4 kPa (90-110 psi)
	Flow:	Minimum, 140 l/min (5 scfm) at rated pressure.
Operating Conditions:	Ventilation:	Minimum 2.5 cm (1") clearance on all sides, with console on a hard flat surface.
	Temperature:	+10º to +40ºC
	Humidity:	10% to 90% non condensing
Storage Conditions:	Temperature:	-30º to +60ºC
	Humidity:	10% to 95% non condensing
Safety Agency Registration:	Underwriters Laboratory (UL) Classified to UL60601-1/Can/CSA C22.2 No. 601.1 Medical Device Class I per UL 60601-1 National Australia Testing Agency (NATA) Type CF equipment (IEC 601). TUV certifications to IEC 601, EN550011, Class B and EN60601-1-2.	

Quarterly Inspections

These inspections should be performed once per quarter. If console fails any of the inspections listed below, contact your Customer Service representative.

1. **Check the physical condition of the power cable, strain relief, and plug.**

   Make sure that there are no frayed ends on the power cable connector, the strain relief is attached, the plug has no bent prongs, and the ground prong in the plug is present and secure. Verify that there are no unacceptable scratches or punctures on the exterior of the AC cord set.

2. **Check for loose or missing screws, sharp edges, or loose connectors.**

   By hand, check the console pneumatic connectors and verify that they are not loose. Verify that all screws are in place on covers. Hold console in both hands and shake in two different directions to verify that there is no loose hardware inside the console.

3. **Perform an external visual inspection for mechanical damage.**

   Verify that there are no unacceptable chips, dents, scratches, or marks on the console enclosure or foot pedal. Verify that the knobs are secured properly and are not loose. Tighten any loose knobs. Make sure that the pneumatic connectors are in working order, not stuck open, and are tight against the console.

4. **Check the front panel indicators.**

   With the console connected to AC power and compressed gas, cycle the Power switch to apply power to the console and verify that:

   a) The green Power LED illuminates.

   b) The EVENT TIME display reads 00:00.

   c) The PROCEDURE TIME display reads 00:00.

   d) The RPM display is blank.

   e) The STALL display is blank.

5. **Check the operation of the turbine pressure gauge.**

   Connect the console to AC power and compressed gas. Starting with the SPEED ADJUST knob fully counterclockwise, verify that clockwise rotation of the SPEED ADJUST knob results in an increased reading on the console TURBINE PRESSURE gauge.

6. **Check the operation of the DYNAGLIDE™ Foot Pedal display.**

   With the console connected to AC power and compressed gas, and with the Dynaglide Foot Pedal connected, turn on the unit, cycle the DYNAGLIDE Feature button on the foot pedal, and verify that the DYNAGLIDE Feature indicator illuminates and goes blank.

7. **Check the operation of the STALL display.**

   Without connecting the advancer (i.e., no fiber optic connector plugged in), activate the foot pedal and check for stall light illumination. Verify that the stall light goes blank when foot pedal is released.

Service Information

Fuse: In the event of a fuse failure, turn off the power and unplug the line cord from the power outlet. The power cord may also be unplugged from the rear of the console to improve fuse access. Using a tool such as a screwdriver, remove the fuse drawer by depressing the locking tab. See Figure 3 below.

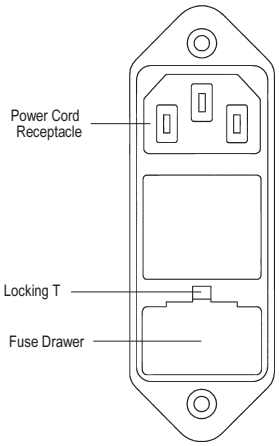

Figure 3
Fuse Replacement

Replace both fuses with the same type and rating as specified on the rear of the console. Reinsert the fuse drawer until the locking tab snaps into place. Reconnect the power cord and restore power to the console. If a fuse fails again, disconnect all power to the console and contact your Customer Service representative.

All other service must be performed by Boston Scientific Corporation personnel. Field repair, other than the console's external fuse replacement, voids all warranties and may not be performed without express authorization from Customer Service.

Appendix C - Running the System From Low Pressure (House) Lines

Note: This appendix does NOT apply to TUV Rotablator™ Consoles.

The Rotablator Rotational Angioplasty System is designed to be operated from compressed gas cylinders via a cylinder regulator. However, if a house air or nitrogen system is available, the control console can be supplied directly, eliminating the need for a cylinder and cylinder regulator. The requirements are as follows:

1. The compressed gas must be air or nitrogen only.
2. The gas must be clean, dry, and oil free.
3. The gas pressure must be between 620.5 kPa (90 psi) and 758.4 kPa (110 psi) at the inlet to the control console.
4. The system must be capable of supplying gas at a rate of 140 l/min (5 scfm) or more.

An adapter fitting is available for the Rotablator™ Console. This fitting has a female quick-connect on one end and .6 cm (¼") MNPT threads on the other. The .6 cm (¼") MNPT end is a standard .6 cm (¼") pipe male fitting and will readily fit most gas handling equipment or connectors on the house lines. The quick-connect mates directly to the connector on the end of the supply hose which normally would attach to a regulator.

Appendix D - Electronic and Electromagnetic Guidance

Guidance and manufacturer's declaration - electronic emissions		
The Rotablator System is intended for use in the electromagnetic environment specified below. The customer or the user of the Rotablator System should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Rotablator System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Rotablator System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Rotablator System is intended for use in the electromagnetic environment specified below. The customer or the user of the Rotablator System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Rotablator System requires continued operation during power mains interruptions, it is recommended that the Rotablator System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Rotablator™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the Rotablator System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Rotablator System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Rotablator System is used exceeds the applicable RF compliance level above, the Rotablator System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Rotablator System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Rotablator System			
The Rotablator System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Rotablator System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Rotablator System as recommended below, according to the maximum output power of the communications equipment.			
Rate Maximum Output Power of Transmitter **W**	**Separation Distance According to Frequency of Transmitter** **m**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Warranty

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

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